The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

**Rescind:**

4729-9-11: Provides the general requirements for the security and control of dangerous drugs by terminal distributors of dangerous drugs (TDDDs).

4729-9-14: Provides the general record keeping requirements for controlled substance dangerous drugs by TDDDs.

4729-9-22: Provides the general record keeping requirements for non-controlled substance dangerous drugs maintained by TDDDs.

Comments on the proposed rules will be accepted until close of business on **July 26, 2019**. Please send all comments to the following email address: Ali.Simon@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov
Business Impact Analysis

RESCINDED PACKAGES

Agency Name: State of Ohio Board of Pharmacy
Agency Contact Info: Cameron McNamee, cameron.mcnamee@pharmacy.ohio.gov
Regulation/Packet Title: Rescission of Security and Record Keeping Rules
Rule Number(s): 4729-9-11; 4729-9-14; 4729-9-22
Date: 7/5/2019
Rule Type:
✓ Rescinded

This form is intended for rule packages in which every rule in the package is being rescinded. New, Amended, No-Change, and Rescind/New rules must use the standard BIA.

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent
1. **Please describe in plain language the regulation that is being rescinded.**
   The following are proposed to be rescinded:

   - **4729-9-11**: Provides the general requirements for the security and control of dangerous drugs by terminal distributors of dangerous drugs (TDDDs).
   - **4729-9-14**: Provides the general record keeping requirements for controlled substance dangerous drugs by TDDDs.
   - **4729-9-22**: Provides the general record keeping requirements for non-controlled substance dangerous drugs maintained by TDDDs.

2. **Why is the regulation being rescinded?**
   *Please be specific (ORC change, request of stakeholders, etc.)*

   The Board is in the process of reorganizing its rules into divisions. Each division will have specific chapters for different licensees (prescriber clinics, outpatient pharmacies, veterinary clinics, EMS, etc.). Each chapter will have its own security and record keeping rules based upon various businesses that are regulated by the Board. To accomplish this, general rules that apply across all license types (such as the three listed in this document) must be rescinded.

3. **Please describe in general terms the adverse impacts to business, including currently impacted industries, in the existing rule(s).**

   - **4729-9-11**: Provides the general requirements for the security and control of dangerous drugs by terminal distributors of dangerous drugs (TDDDs). Generally, this requires all drugs maintained by TDDDs to be secured to prevent unauthorized access. It also requires personal supervision of dangerous drugs by a pharmacist or a prescriber (depending on the license type). This requires certain security methods such as locked cabinets, electronic barriers (i.e. alarms), and other methods to deter and detect the diversion of drugs. It also requires that a prescriber or pharmacist be on-site when drugs are being accessed to deter and detect the diversion of drugs.
   - **4729-9-14**: Provides the general record keeping requirements for controlled substance dangerous drugs by TDDDs. Requires records to be kept for all controlled substances received, administered, personally furnished, dispensed, sold, destroyed, or used. Also, requires the use of positive identification (see OAC 4729-5-01 (N)) for all drugs administered or dispensed.
4729-9-22: Provides the general record keeping requirements for non-controlled substance dangerous drugs maintained by TDDDs. Requires records to be kept for all non-controlled substances received, administered, personally furnished, dispensed, sold, destroyed, or used. Also, requires the use of positive identification (see OAC 4729-5-01 (N)) for all drugs administered or dispensed.

4. Are there other regulations (either existing or to be created) which will replace the regulation being rescinded or which will now apply because this regulation is being rescinded? This can include rules, statute, federal regulations, agency policies, or industry standards etc.

Yes. As previously noted, new rules are in the process of being promulgated that will take the place of these general rule provisions. The new rules are based upon business type, which should provide additional flexibility to licensees.

5. Does the rescission of this regulation eliminate flexibility or create more adverse impacts for stakeholders? If yes, please describe stakeholder outreach and justify the impacts.

No. The rescission of this rule should provide additional flexibility to licensees. For example, current requirements for record keeping require prescribers to use positive identification for all drugs administered. In rules that have been proposed, the requirement has been shifted to only require positive identification for controlled substances. This should reduce overall regulatory costs for prescriber licensees.
4729-9-22 Records of dangerous drugs. (RESCIND)

Each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, personally furnished, distributed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a dangerous drug must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.

(A) Records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt.

(B) Records of administering, dispensing, personally furnishing, or using dangerous drugs shall contain a description of the kind and quantity of the dangerous drugs administered, dispensed, sold, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the dangerous drug was administered, dispensed, or used.

(C) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the prescriber or responsible person that performed the destruction, and if used the positive identification of the person that witnessed the destruction.

(D) Records of dangerous drugs, other than controlled substances, administered, personally furnished, dispensed, or used which become a permanent part of the patient's medical record shall be deemed to meet the requirements of paragraph (B) of this rule.

(E) All records of receipt, distribution, personally furnishing, administering, dispensing, selling, destroying, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located and upon request provided to a state board of pharmacy officer, agent, and/or inspector within three working days, excluding weekends and holidays. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.
4729-9-14 Records of controlled substances. (RESCIND)

(A) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, personally furnished, dispensed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a controlled substance must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.

(1) Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from whom received, and the date of receipt.

(2) Records of administering, dispensing, personally furnishing or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, personally furnished or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the controlled substance was administered, dispensed, or used.

(3) Records of drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the name and address requirements of paragraph (A)(2) of this rule.

(4) Destruction of controlled substances shall be conducted in accordance with rule 4729-9-06 of the Administrative Code.

(B) Each prescriber or terminal distributor of dangerous drugs shall maintain an inventory of all controlled substances as follows:

(1) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

(a) The name of the substance.

(b) The total quantity of the substance.

(i) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per milliliter).

(ii) The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial).

(iii) The number of commercial containers of each such finished form (e.g., three one-hundred-tablet bottles or ten one-milliliter vials).

(c) If the substance is listed in schedule I or II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents.
(d) If the substance is listed in schedule III, IV, or V, the prescriber or terminal distributor of dangerous drugs may make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.

(2) A separate inventory shall be made for each place or establishment where controlled substances are in the possession or under the control of the prescriber or terminal distributor. Each inventory for each place or establishment shall be kept at the place or establishment.

(3) An inventory of all stocks of controlled substances on hand on the date the prescriber or terminal distributor first engages in the administering, dispensing, or use of controlled substances. In the event the prescriber or terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

(4) Each prescriber or terminal distributor of dangerous drugs shall take a new inventory of all stocks of controlled substances on hand every year following the date on which the initial inventory is taken.

(5) When a substance is added to the schedule of controlled substances by the federal drug enforcement administration or the state board of pharmacy, each prescriber or terminal distributor of dangerous drugs shall take an inventory of all stock of such substance on hand at that time.

(C) All records of receipt, distribution, administering, dispensing, personally furnishing, inventory, destruction, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of controlled substances. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.
4729-9-11 Security and control of dangerous drugs. (RESCIND)

A pharmacist, prescriber, and responsible person pursuant to rule 4729-5-11 of the Administrative Codeshall provide supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws as required in section 4729.55 of the Revised Code, by the following procedures:

(A) In a pharmacy:

(1) Except as provided in paragraph (A)(2) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, at all times in order to deter and detect theft or diversion;

(2) Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:

(a) The prescription department or stock of dangerous drugs must be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time the pharmacist is not present. Such a barrier, before being put into use, must be approved by the state board of pharmacy.

(b) The prescription department must contain all dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, and every other item or product that requires the personal supervision or sale by a pharmacist.

(c) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the prescription department.

(d) Except as provided in rule 4729-17-03 of the Administrative Code, only a pharmacist may have access to the prescription department or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, exempt narcotics, hypodermics, poisons, and any other item or product that requires the personal supervision or sale by a pharmacist.

(e) No prescription, dangerous drug, exempt narcotic, hypodermic, nor any other item or product that requires the personal supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the prescription department is closed.
(f) New or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.

(g) If a pharmacy utilizes a board approved delivery system that securely stores and releases a dispensed prescription drug to a patient the pharmacy must be open for business and a pharmacist must be physically present and available for consultation, unless otherwise authorized by the board.

(h) Any designated area outside the prescription department at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, exempt narcotics, hypodermics, poisons, records relating to the distribution of dangerous drugs except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, and every other item or product that requires the personal supervision or sale by a pharmacist shall meet the following requirements:

(i) The designated area shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect unauthorized entry. Such a barrier, before being put into use, must be approved by the state board of pharmacy.

(ii) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy.

(iii) Authorized personnel may have access if there is on-site supervision by a pharmacist.

(3) Areas designated for the dispensing, compounding, and storage of dangerous drugs shall meet the security requirements in rule 4729-9-05 of the Administrative Code. No person may be within the physical confines of the area designated for the dispensing, compounding, and storage of dangerous drugs unless under the personal supervision of a pharmacist.

(B) In other terminal distributors of dangerous drugs, including but not limited to, emergency medical services pursuant to division (C) of section 4729.54 of the Revised Code, first-aid departments pursuant to rule 4729-9-03 of the Administrative Code, approved laboratories pursuant to paragraph (D) of rule 4729-13-01 of the Administrative Code, and animal shelters pursuant to paragraph (A) of rule 4729-14-01 of the Administrative Code, shall comply with all of the following:

(1) Dangerous drugs, exempt narcotics, uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms, hypodermics and poisons must be stored in an area secured by either a physical barrier with suitable locks, which may include a substantially constructed cabinet, and/or an electronic barrier to deter and detect unauthorized access;
(2) All records relating to the dispensing, distribution, personal furnishing and sale of dangerous drugs shall be maintained on-site under appropriate supervision and control to restrict unauthorized access.

(3) Paragraph (B)(1) of this rule does not apply to hypodermics at veterinary facilities if all of the following conditions are met:

(a) During non-business hours, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, and/or an electronic barrier to deter and detect unauthorized access;

(b) During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections.

(C) A pharmacist, prescriber, or responsible person for a terminal distributor of dangerous drugs license pursuant to rule 4729-5-11 of the Administrative Code who has signed as being responsible for a terminal distributor of dangerous drugs license is responsible to monitor for suspicious orders, unusual usage, or questionable disposition of dangerous drugs.

(D) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board. Records relating to the distribution of dangerous drugs shall be maintained in a secure manner that ensures the integrity of the information.

(E) Only individuals authorized under state laws or rules shall have unsupervised access to dangerous drugs.